UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

FEDERAL TRADE COMMISSION, **STATE OF ILLINOIS,** and **STATE OF MINNESOTA,** *Plaintiffs,* v. **GTCR, LLC,** **GTCR BC HOLDINGS, LLC,** and **SURMODICS, INC.,** *Defendants*.	**Case No. 1:25-cv-02391** **Hon. Jeffrey I. Cummings**

PLAINTIFFS' MEMORANDUM OF LAW
IN SUPPORT OF THEIR MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

The Federal Trade Commission ("FTC" or the "Commission") and the States of Illinois and Minnesota ask this Court to preserve the status quo and preliminarily enjoin GTCR, LLC and GTCR BC Holdings, LLC (collectively, "GTCR") from acquiring Surmodics, Inc. ("Surmodics"), the largest supplier of outsourced hydrophilic coatings for medical devices in the United States, pending a merits trial before the FTC's administrative court. Today, GTCR has a controlling interest in Biocoat, Inc. ("Biocoat"), the second-largest supplier of outsourced hydrophilic coatings for medical devices in the United States.

Hydrophilic coatings are a key input used to enhance the safety and efficacy of medical devices that treat strokes, heart disease, and other life-threatening conditions by providing the lubricity needed for a physician to safely navigate the device through a patient's body to the heart, brain, or other vital organs without damaging sensitive tissue. Biocoat and Surmodics compete fiercely to sell these coatings and related services to medical device companies. Indeed, when [redacted]. PX2006 at 002. GTCR and their affiliates and subsidiaries' proposed acquisition of Surmodics (the "Proposed Acquisition") represents a permanent truce between Biocoat and Surmodics, ending the intense competition that has spurred each of them to offer better products and services at lower prices.

The Proposed Acquisition will not benefit customers of outsourced hydrophilic coatings, nor will it benefit patients. If GTCR is allowed to acquire Surmodics—Biocoat's "[redacted]"—the combined company will amass more than [redacted] percent of the market for a critical component of lifesaving medical devices. *See* PX2048 ([redacted]

[redacted]). With this market power, GTCR will be able to raise prices and reduce quality and innovation for outsourced hydrophilic coatings. The Proposed Acquisition will eliminate significant head-to-head competition between Biocoat and Surmodics and enable GTCR to execute its "[redacted]" in the outsourced hydrophilic coatings market. [redacted]. PX1343 at 007-008 ([redacted]).

The commanding market share of a combined Biocoat-Surmodics, as well as the significant increase in market concentration for outsourced hydrophilic coatings, render the Proposed Acquisition presumptively unlawful under the 2023 Merger Guidelines issued jointly by the FTC and the U.S. Department of Justice (hereinafter, the "Merger Guidelines"). The elimination of head-to-head competition between Biocoat and Surmodics provides an additional basis for the Proposed Acquisition's illegality under the Merger Guidelines. Defendants cannot show that entry, efficiencies, or any other countervailing factors will outweigh the harm that will result from the Proposed Acquisition.

To prevent harm to competition in the market for outsourced hydrophilic coatings, the Commission voted to issue an administrative complaint and authorized staff to seek a preliminary injunction to halt the Proposed Acquisition pending a full trial on the merits to resolve the merger's legality. The Commission, the State of Illinois, and the State of Minnesota (collectively, "Plaintiffs") now ask this Court to preserve the status quo until the FTC "can perform its adjudicatory function." *FTC v. IQVIA Holdings Inc.*, 710 F. Supp. 3d 329, 348 (S.D.N.Y. 2024).

STATEMENT OF FACTS

I. Hydrophilic Coatings Are Essential for Lifesaving Interventional Medical Devices

Biocoat and Surmodics have spent decades developing proprietary hydrophilic coatings which are applied to highly sensitive, complex medical devices, such as catheters, guidewires, and stents, used in high-stakes neurovascular and cardiovascular procedures. PX7023 ([redacted]) at 26:20-27:1; PX2021 at 027 ([redacted]). Although hydrophilic coatings represent a relatively small portion of the total cost of developing and launching a medical device, they are essential for ensuring the device's performance and safety. PX7045 ([redacted]) at 70:18-21; PX7023 ([redacted]) at 101:4-102:15,109:2-15. A hydrophilic coating, as the name implies, is a "water loving" solution designed to increase the lubricity, or slipperiness, of a medical device, enabling physicians to navigate the device through small, sensitive structures like blood vessels without causing abrasion. PX7024 ([redacted]) at 107:7-16, 107:23-108:4, 108:20-109:10; PX7025 ([redacted]) at 19:14-21:5. Any excess friction created by a medical device's movement may cause damage to vital organs within the patient's body. *See* PX7018 (Borgaonkar (Heraeus) Dep.) at 22:22-23:14. Hydrophilic coatings provide an unmatched level of performance that physicians need to safely and effectively conduct certain interventional procedures. *See* PX7044 ([redacted]) at 26:20-27-4 ("[redacted]").

Because hydrophilic coatings are a "[redacted]" medical device original equipment manufacturers ("OEMs") place a premium on selecting a high-quality, reliable hydrophilic coating. PX1593 at 008 ([redacted]). OEMs value established suppliers,

like Biocoat and Surmodics, that have a proven record of coating devices approved by the U.S. Food and Drug Administration ("FDA") and have employees with the requisite knowledge and experience to optimize the coating's performance for their devices. PX7039 (Welsh (Alembic) Dep.) at 94:14-95:7 (OEM indicating they "[redacted]"); PX7016 ([redacted]) at 146:24-147:9 ([redacted]).

As a result of these rigorous standards, and because manufacturing hydrophilic coatings requires significant resources, know-how, and equipment, many OEMs rely on specialized suppliers like Biocoat and Surmodics for their hydrophilic coating needs, rather than developing coatings themselves. PX7039 (Alembic (Welsh) Dep.) at 111:4-112:14; *see infra* at 14, 20. The use of dedicated coating suppliers has only increased as devices have become more complex and subject to enhanced regulatory scrutiny. PX7027 ([redacted]) at 116:5-117:8; PX1091 at 010 ([redacted]).

To ensure a coating adheres and performs optimally, hydrophilic coating suppliers work with customers to adjust the cleaning protocol, chemical composition, application process, and curing time for applying the hydrophilic coating to the substrate (i.e., surface) of the customer's device. PX7015 ([redacted]) at 47:16-49:5. Once applied, the coating dries and binds to the device, typically through one of two ways: thermal or ultraviolet light ("UV") curing. For thermal curing, the coated devices are dried and cured in an oven. With UV curing, the coated devices are placed in a chamber and exposed to high-intensity UV light. Biocoat offers a thermal-cured hydrophilic coating under the brand name Hydak and a UV-cured hydrophilic coating, Hydak UV. PX7015 ([redacted]) at 82:6-11. Surmodics offers UV-cured

hydrophilic coatings under the brand names Serene, Pristyne, and Preside, among others. PX7020 ([redacted]) at 50:6-17. Both thermal and UV curing are suitable for the vast majority of medical devices to which hydrophilic coatings are typically applied. PX5001 ([redacted]) ¶ 5 ("[redacted]"); PX7024 ([redacted]) at 168:10-170:18 ([redacted]); PX1427 at 017 ([redacted]); *compare* PX1313 at 012 ([redacted]), *with* PX1313 at 071 ([redacted]).

When choosing a hydrophilic coating, customers primarily focus on the coating's performance, which includes the coating's lubricity, durability, particulate count, and biocompatibility (i.e., the solution's ability to perform in the body without adverse effects). *See* PX7023 ([redacted]) at 41:13-44:13. Beyond performance, many customers will consider additional factors when choosing a hydrophilic coating, such as the supplier's reputation, price, customer service, and ability to provide coating services and assist with the FDA approval process. *See* PX7034 ([redacted]) at 189:5-191:20; PX7045 ([redacted]) at 35:6-16; PX7020 ([redacted]) at 51:12-54:12 ([redacted]); PX7025 ([redacted]) at 89:19-90:5. Due to the time and expense associated with developing a medical device, customers also value established coating suppliers with strong reputations for quality and longevity, like Biocoat and Surmodics. PX7045 ([redacted]

[redacted]) at 90:19-91:18; PX7021 ([redacted]) at 143:7-15; PX7032 ([redacted]) at 167:7-10.

Customers place a premium on suppliers that can help optimize a hydrophilic coating's performance on a device. Coating optimization, which involves adjusting the formulation of the coating and/or the coating application protocol, is an intensive, often months or years long process that involves regular communication between the hydrophilic coating supplier and customer and is essential for maximizing the performance of the medical device and receiving FDA clearance. PX7036 ([redacted]) at 72:6-75:10; PX7000 ([redacted]) at 136:21-137:3. These services require specialized facilities with clean rooms, equipment for R&D and production runs, and ISO certification. PX7024 ([redacted]) at 98:21-100:21, 102:9-105:11. Both at the development stage, and over the lifetime of a device, it is "[redacted]" to address any issues that may arise. PX7023 ([redacted] at 50:9-1); *see also, e.g.*, PX7039 (Welsh (Alembic) Dep.) at 114:1-23 (coating knowledge and services in support of product development are important when choosing a hydrophilic coating supplier).

II. Biocoat and Surmodics Are the Largest Competitors in the Outsourced Hydrophilic Coatings Market

Ordinary course documents and expert analysis paint a clear picture of Biocoat and Surmodics as the top two competitors in the outsourced hydrophilic coatings market. Providers of outsourced hydrophilic coatings and associated services in the United States generated approximately $84.6 million in revenue in 2024. PX4000 (Expert Report of Dr. Aaron Fix) at 142, Exhibit 1 (hereinafter, "Fix Expert Report"). Biocoat and Surmodics are the longstanding market leaders and are responsible for over [redacted] percent of that revenue, with Surmodics

generating approximately $[redacted] million and Biocoat generating approximately $[redacted] million in U.S. hydrophilic coating revenue in 2024. PX4000 (Fix Expert Report) at ¶¶ 35, 37. The next largest supplier behind Biocoat and Surmodics is Harland Medical Systems ("Harland") with $[redacted] million in U.S. hydrophilic coating revenue. PX4000 (Fix Expert Report) at ¶ 40. No other supplier generated more than $[redacted] million in U.S. hydrophilic coating revenue in 2024. PX4000 (Fix Expert Report) at 142, Exhibit 1; *see also* PX7034 ([redacted]) at 141:17-142:7, 221:14-222:13, 224:19-225:9 ([redacted]); PX5007 ([redacted]) at ¶ 5 ("[redacted]").

Recent ordinary course documents and testimony from [redacted], have identified Biocoat and Surmodics as the number two and number one suppliers of outsourced hydrophilic coatings, respectively. *See, e.g.*, PX1014 at 027 ([redacted]) ("[redacted]"); PX7000 ([redacted]) at 258:8-15 ([redacted]); PX1146 at 001 ([redacted]) ("[redacted]").

Customers and competitors agree. [redacted] PX5009 ([redacted]) at ¶ 6; *see also* PX3000 at 021 ([redacted])

(“[redacted]”); PX7027 ([redacted]) at 37:6-38:6 ([redacted]).

[redacted]

PX2048 at 001 ([redacted])

III. GTCR Intends to Combine Biocoat and Surmodics to Advance its “[redacted]” In the Outsourced Hydrophilic Coatings Market

The Proposed Acquisition is one step in GTCR’s strategy to reap the financial benefits of a market roll up on behalf of its investors at the expense of medical device manufacturers and patients who benefit from lifesaving devices. GTCR executives [redacted]. PX0016 at 005, 007, 008 ([redacted]); PX0017 at 003 ([redacted]). In November 2022, GTCR spent $[redacted] to become the controlling investor in Biocoat, calling it an

" PX0031 at 003 ( ); PX0016 at 007 ( ); PX6006 at 001 (GTCR Press Release, Nov. 2, 2022) (announcing majority investment in Biocoat). During its diligence for the Biocoat investment, GTCR highlighted its "

." PX0016 at 007, 064.

GTCR then set out to use Biocoat as a platform to execute on its trademarked "Leaders Strategy," which, as GTCR's website explains, involves "partner[ing] with strong incumbent management teams to provide them capital to execute transformational opportunities, like acquiring a significant competitor." PX6020 at 001. From the outset, GTCR

. PX0010 at 007, 014 ( ). A January 2023 Biocoat Board presentation

PX1158 at 075.

GTCR and Biocoat immediately

PX1159 at 011 ( ).

PX1093 at 001.

[redacted]. PX7006 ([redacted]) at 64:2-66:15.

After being [redacted], GTCR moved its focus to Surmodics, aiming to combine the top two hydrophilic coating suppliers through the Proposed Acquisition. But GTCR does not plan to stop there. In keeping with its plan to "[redacted]. PX1592 at 007, 017, 023 ([redacted]); PX7029 ([redacted]) at 167:22-173:8. [redacted]. *See* PX1671 at 001 ([redacted]. PX1192 at 001 ([redacted]).

LEGAL STANDARD

Section 13(b) of the FTC Act authorizes the Commission to seek a preliminary injunction to preserve the status quo pending completion of the administrative trial on the merits of the underlying antitrust claims "[u]pon a proper showing that, weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest." 15 U.S.C. § 53(b); *FTC v. Elders Grain, Inc.*, 868 F.2d 901, 903 (7th Cir. 1989). To establish likelihood of success on the merits, the FTC need not establish a "certainty" or "even a high probability" of anticompetitive harm. *Elders Grain*, 868 F.2d at 906. Instead, "at this preliminary phase it just has to raise substantial doubts about [the] transaction." *FTC v. OSF Healthcare Sys.*,

852 F. Supp. 2d 1069, 1074 (N.D. Ill. 2012) (quotations omitted); *see also Elders Grain*, 868 F.2d at 906 (Section 13(b) "requires a prediction, and doubts are to be resolved against the transaction"); *FTC v. Kroger Co.*, 2024 WL 5053016, *1 (D. Or. Dec. 10, 2024) ("The court is not asked to make a final determination on whether the proposed merger violates Section 7, but rather to make only a preliminary assessment of the merger's impact on competition.") (internal quotations omitted); *FTC v. IQVIA Holdings Inc.*, 710 F. Supp. 3d 329, 348 (S.D.N.Y. 2024).

"The public has strong interests in the effective enforcement of the antitrust laws and in preserving [the FTC's] ability to order effective relief if it succeeds after a trial on the merits." *FTC v. Advoc. Health Care*, 2017 WL 1022015, *16 (N.D. Ill. Mar. 16, 2017). As a result, public equities must "receive far greater weight" than private equities. *FTC v. World Travel Vacation Brokers, Inc.*, 861 F.2d 1020, 1030 (7th Cir. 1988) (quotations omitted). If the FTC demonstrates a likelihood of success on the merits, "a countershowing of private equities alone would not suffice to justify denial of a preliminary injunction barring the merger." *Elders Grain*, 868 F.2d at 903 (quotations omitted); *see also OSF Healthcare*, 852 F. Supp. 2d at 1094 ("The equities will often weigh in favor of the FTC, since the public interest in effective enforcement of the antitrust laws was Congress's specific public equity consideration in enacting the provision") (quotations omitted).

Section 7 of the Clayton Act, designed to halt harm from an anticompetitive merger "in its incipiency," bars mergers "the effect of [which] may be substantially to lessen competition, or to tend to create a monopoly" in "any line of commerce or . . . activity affecting commerce in any section of the country." *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 589 (1957) (quoting 15 U.S.C. § 18). Under the burden-shifting framework used to evaluate whether a merger is unlawful under Section 7 of the Clayton Act, Plaintiffs must first establish a *prima*

facie case that a proposed acquisition is unlawful. *See United States v. Baker Hughes, Inc.*, 908 F.2d 981, 982-83 (D.C. Cir. 1990); *OSF Healthcare Sys.*, 852 F. Supp. 2d at 1074. If Plaintiffs establish a *prima facie* case, the burden of production shifts to Defendants to produce evidence showing that Plaintiffs' evidence does not accurately depict the merger's likely competitive effects. *United States v. Marine Bancorp.*, *Inc.*, 418 U.S. 602, 631 (1974). If Defendants meet their burden, the burden shifts back to Plaintiffs to produce additional evidence of competitive harm. *Saint Alphonsus Med. Ctr. Nampa Inc. v. St. Luke's Health Sys*, 778 F.3d 775, 783 (9th Cir. 2015). The stronger the *prima facie* case, "the more evidence the defendant must present to rebut it successfully." *FTC v. H.J. Heinz*, 246 F.3d, 708 725 (D.C. Cir. 2001) (quotations omitted).

ARGUMENT

I. The Commission Is Likely to Succeed on the Merits

The Commission is likely to succeed on the merits in the administrative proceeding because the Proposed Acquisition satisfies two independent bases for finding that it may substantially lessen competition. In the relevant market for outsourced hydrophilic coatings in the United States, the Proposed Acquisition results in market shares and concentrations that establish a presumption that the Proposed Acquisition is illegal, meaning that Plaintiffs are entitled to a preliminary injunction unless Defendants can meet their burden to rebut the presumption (which they cannot). *See United States v. Philadelphia Nat'l Bank*, 374 U.S. 321, 363-64 (1963); *OSF Healthcare Sys.*, 852 F. Supp. 2d at 1074-75. In addition, the elimination of fierce head-to-head competition between Biocoat and Surmodics may result in a substantial lessening of competition by combining the two top outsourced hydrophilic coating suppliers in the United States. *See, e.g.*, *ProMedica Health Sys., Inc. v. FTC*, 749 F.3d 559, 568-70 (6th Cir. 2014) (describing how "the elimination of competition between two firms that results from their merger may alone constitute a substantial lessening of competition") (quotations omitted).

A. The Relevant Product Market Is Outsourced Hydrophilic Coatings

The relevant product market is the "line of commerce" affected by a proposed merger. *Brown Shoe Co. v. United States*, 370 U.S. 294, 324 (1962). Courts frequently define relevant markets using two analyses—the *Brown Shoe* practical indicia and the hypothetical monopolist test ("HMT"). *Id* at 325*; FTC v. Advoc. Health Care Network*, 841 F.3d 460, 473 (7th Cir. 2016) (applying the HMT to define a relevant product market).

In *Brown Shoe*, the Supreme Court set forth "practical indicia" for defining a relevant product market, which include "(1) the industry or public recognition of the submarket as a separate economic entity, (2) the product's peculiar characteristics and uses, (3) unique production facilities, (4) distinct customers, (5) distinct prices, (6) sensitivity to price changes, and (7) specialized vendors." *Beatrice Foods Co. v. FTC*, 540 F.2d 303, 308 (7th Cir. 1976) (citing *Brown Shoe*, 370 U.S. at 325). "All the factors need not be satisfied for the Court to conclude that the FTC has identified a relevant market." *IQVIA*, 710 F. Supp. 3d at 355 (citing *FTC v. Staples*, 970 F. Supp. 1066, 1075 (D.D.C. 1997)). Courts also consider the HMT, which asks whether a hypothetical firm that controls the entire candidate product market could "raise prices profitably a bit above competitive levels," also referred to as a small but significant non-transitory increase in price ("SSNIP"). *Advoc. Health Care Network*, 841 F.3d at 465.

Here, the *Brown Shoe* practical indicia and application of the HMT demonstrate that outsourced hydrophilic coatings is a relevant product market in which to assess the competitive effects of the Proposed Acquisition. This relevant product market includes both UV-cured and thermal-cured hydrophilic coatings because they are reasonably interchangeable for a substantial number of cases. PX5001 ([redacted]) ¶ 5 ("[redacted]"); *supra* at 5-6. Both thermal

and UV curing are suitable for the vast majority of medical devices to which hydrophilic coatings are typically applied. PX5001 ( ) ¶ 5 (“ ”); PX7024 ( ) at 168:10-170:18 ( ); PX1427 at 017 ( ); *compare* PX1313 at 012 ( ) ( ), *with* PX1313 at 071 ( ) ( ). The relevant product market excludes other types of coatings, like hydrophobic coatings, because customers of hydrophilic coatings do not view other types of coatings as reasonable substitutes. PX5003 ( ) ¶ 2 (“ ”); *infra* at 16-17. Further, while some medical device companies have their own proprietary hydrophilic coatings, in-house coatings are properly excluded from the relevant market. In-house coatings are not sold to other medical device manufacturers, and manufacturers that have in-house coatings often rely on outsourced coatings from companies like Biocoat and Surmodics. PX7027 ( ) at 113:17-22 ( ); PX7018 (Borgaonkar (Heraeus Medical) Dep.) at 85:7-19; PX1677 at 012 ( ); *infra* at 20-21.

i. *Brown Shoe* Practical Indicia

Indicium 1: Peculiar Characteristics and Uses. Hydrophilic coatings provide a level of lubricity unmatched by other types of coatings. *See, e.g.*, PX7039 (Welsh (Alembic) Dep.) at 69:3-70:9 ([redacted]); PX7025 ([redacted]) at 19:14-21:5 ([redacted]). [redacted], explained that [redacted]. *See* PX7024 ([redacted]) at 233:8-236:22, 243:22-245:25, 240:19-241:16 ([redacted]); PX5006 ([redacted]) ¶ 2 ("[redacted]").

Due in part to the difference in lubricity, hydrophilic and hydrophobic coatings have distinct uses and applications. Hydrophilic coatings are generally used on medical devices that require greater lubricity to move through the body, like neurovascular catheters, while hydrophobic coatings, which "[redacted]" and may result in higher friction than hydrophilic coatings, are more often used on devices like pacemakers. PX7008 ([redacted]) at 21:4-14. When both hydrophilic and hydrophobic are used on the same device, hydrophilic coatings are typically applied to the distal end of a device (i.e., the end farther from the physician that travels deeper into the patient's body), which "[redacted]" and therefore "[redacted]." PX7023 [redacted]) 35:16-36:8; PX7024 ([redacted]) 234:21-235:6 ([redacted]

[redacted]

[redacted]”). By contrast, a hydrophobic material like PTFE is typically used on the proximal end of a device (i.e., the end closer to the physician), which experiences less friction during interventional procedures. PX7008 ([redacted]) at 21:4-22; *see also* PX7038 ([redacted]) at 18:4-20, 27:15-28:5 ([redacted]). Customers typically do not consider both hydrophilic and hydrophobic coatings for the same use cases. *See* PX7006 ([redacted]) at 18:8-20 ([redacted]); PX7027 ([redacted]) at 35:24-36:16 ([redacted]).

Thermal-cured and UV-cured hydrophilic coatings are largely appropriate for the same uses. PX7027 ([redacted]) at 41:22-42:3 ([redacted]); PX7025 ([redacted]) at 53:3-6; PX5002 ([redacted]) ¶¶ 5-6 (“[redacted]”); PX7048 ([redacted]) at 70:10-11 (“[redacted]”). Biocoat’s [redacted] *Compare* PX1313 at 012 ([redacted]), *with* PX1313 at 071 ([redacted]); *see also* PX1290 at 001 ([redacted]); PX1674 at 009 ([redacted]

[redacted]). Likewise, [redacted] [redacted]) at 192:11-23. [redacted] [redacted] similarly testified, "[redacted] [redacted] [redacted]." PX7020 ([redacted]) at 68:4-14.

UV and Thermal Coating Technologies

HYDAK® UV UV CURE HYDROPHILIC COATINGS		HYDAK®
Ultraviolet (UV) Lighting System	**Type of Curing Machine**	Heat via Oven
Neurovascular, Cardiovascular, Peripheral Vascular	**Market Applications**	Neurovascular, Cardiovascular, Peripheral Vascular, Ophthalmology
Yes	**Bi-laminar Platform**	Yes
Ethylene Oxide (EtO), E-Beam and Gamma	**Sterilization Methods**	Ethylene Oxide (EtO), E-Beam and Gamma
Outer Diameter (OD)	**Inner Diameter (ID) vs Outer Diameter (OD) Coating Application**	Inner Diameter (ID) & Outer Diameter (OD)

PX6009 at 002-003 (Biocoat, Hydak Hydrophilic Coatings)

Customers also consistently testified there are no reasonable alternatives to outsourced hydrophilic coatings. *See* PX7039 (Welsh (Alembic) Dep.) at 69:20-70:9; PX7013 (Senn (Integer) IH) at 15:7-18; PX7008 ([redacted]) at 21:4-9; PX5009 ([redacted]) ¶ 3; PX7038 ([redacted]) at 90:4-22. Because numerous interventional medical devices have been FDA-approved with a hydrophilic coating, customers consider hydrophilic coatings as the industry standard and are hesitant to switch to another type of

medical coating as doing so would significantly increase regulatory risk. *See* PX7014 (Hatcher (Switchback) Dep.) at 67:10-69:1 (hydrophilic coatings are the industry standard because of the significant number of FDA-approved devices with hydrophilic coatings).

Indicium 2: Industry Recognition. Industry participants, including Defendants, recognize outsourced hydrophilic coatings as a distinct market from other types of coatings. *See supra* at 15-18. Defendants' ordinary course documents repeatedly analyze their market share and competitive position in this market. For example, [redacted] *See* PX7000 ([redacted]) at 112:20-113:4; PX1026 at 028 (*see* inset).

[redacted]

PX1026 at 028 ([redacted])

In February 2025, [redacted] "[redacted]." [redacted]

[redacted] PX1294 at 015 ([redacted]); PX7015 ([redacted]) at 164:20-24 ([redacted]); *see also* PX1171 at 009 ([redacted]); PX2053 at 009 ([redacted]) ([redacted]).

Evidence from hydrophilic coating suppliers supports an outsourced hydrophilic coatings market and makes clear that both UV- and thermal-cured hydrophilic coatings are part of this market. Third-party competitors indicated they compete against both UV- and thermal-cured hydrophilic coatings. *See* PX7019 ([redacted]) at 57:22-58:21 ([redacted]); PX7027 ([redacted]) at 41:22-42:10 ([redacted]). For example, [redacted]. PX7034 ([redacted]) at 199:17-201:13 ([redacted]); *see also* PX3080 at 002 ([redacted]) ([redacted]).

Customers likewise consider UV-cured and thermal-cured hydrophilic coatings to be substitutable for a substantial number of use cases. *See, e.g.*, PX7025 ([redacted]) at

53:3-54:2 ([redacted]); PX7045 ([redacted]) at 49:13-17 ([redacted] PX5002 ([redacted]) ¶¶ 5-6; *see also* PX3009 ([redacted]) ([redacted]). [redacted] PX5006 ([redacted]) ¶ 5.

Evidence from Defendants also supports an outsourced hydrophilic coatings market that excludes in-house coatings. Defendants' ordinary course documents and testimony consistently refer to the "outsourced" hydrophilic coatings market. PX1145 at 001 ([redacted] (" [redacted] "); PX1095 at 005 ([redacted]) (" [redacted] "). Hydrophilic coating competitors do not consider in-house coatings as meaningful competition for their outsourced solutions. PX5001 ([redacted]) ¶ 6; *see also*

PX1201 at 014 ( ) (“ .”).

Evidence from other industry participants similarly distinguishes outsourced hydrophilic coating suppliers from in-house suppliers. *See* PX7019 ( ) at 98:17-99:4 ( ); PX7041 ( ) at 99:2-10 (”); PX7009 ( ) at 77:18-78:12 (“ .”); PX7027 ( ) at 113:18-22; PX5002 ( ) ¶15 (“ .”).

Indicium 3: Specialized Vendors. Hydrophilic coating suppliers are specialized vendors that provide not only hydrophilic coatings products, but also important services that customers value, which may include fast turnaround time, optimization, coating application services, and assistance with regulatory approval. PX2267 at 004, 013-014; PX7020 ( ) at 40:15-41:11. For example, when discussing selection of a hydrophilic coating supplier, PX7022 ( ) at 148:24-149:3. Other medical device manufacturers have echoed this preference for suppliers that can offer coating services and fast turnaround times. *See* PX5002 ( ) ¶ 13 (

[redacted]); PX7009 ([redacted]) at 71:10-73:7 ([redacted]).

Customers also prefer a coating supplier that specializes in hydrophilic coatings and does not also have a medical device business in its portfolio. [redacted]. PX7022 ([redacted]) at 151:1-152:17; PX7009 ([redacted]) at 84:18-87:19; *see also* PX1524 at 021 ([redacted].

Customers place a premium on suppliers that can help optimize a hydrophilic coating's performance on a device, both at the development stage and over the life of a device. [redacted] PX5002 ([redacted]) ¶ 4. Other medical device companies, such as [redacted] are "[redacted]" on a device's capability and therefore need to work with the coating supplier to "[redacted]" one of the supplier's core offerings. PX7023 ([redacted]) at 50:20-51:7. Even after a device is commercialized, "[redacted]

[redacted]. PX7023 ([redacted]) at 50:9-19.

[redacted]

PX7009 ([redacted]) at 34:7-25; *see also* PX7012 (Hatcher (Switchback) IH) at 46:4-7, 60:20-62:10; PX7021 ([redacted]) at 148:3-24.

To provide these specialized products and services, Biocoat and Surmodics have retained personnel with advanced degrees in chemistry or chemical engineering. PX1524 at 008 ("[redacted]"). These scientists and engineers, many of whom have extensive experience in the hydrophilic coatings industry, not only help develop the latest hydrophilic coating technologies upon which customers (and ultimately patients) rely, but they also work with medical device companies to optimize the coating to meet the needs of a particular device. *Supra* at 4, 6-7, 23.

Customers turn to specialized vendors like Biocoat and Surmodics, rather than develop their own coatings in-house, precisely because Biocoat and Surmodics have spent decades researching and developing the highest-performing and safest hydrophilic coatings possible. *See* PX7023 ([redacted]) at 59:12-60:4 ([redacted]); PX1305 at 036 ([redacted]) ([redacted]); *see also supra* at 14, 20. Even customers that have their own in-house coating frequently rely on outsourced coating providers because of the superior performance of their coatings. *See* PX7021 ([redacted]) at

156:15-157:5 ([redacted]); PX7040 ([redacted]) at 11:8-23, 70:14-71:20 ([redacted]).

Indicium 4: Distinct Prices. Hydrophilic coatings are significantly more expensive than other types of coatings. Customers of hydrophilic coatings testified that hydrophilic coatings typically cost approximately six times as much as hydrophobic coatings. PX7022 ([redacted]) at 145:7-24 ([redacted]); PX7040 ([redacted]) at 181:20-182:13 ([redacted]).

Prices for thermal-cured and UV-cured hydrophilic coatings, however, are comparable. [redacted]. PX1666 at 002 ([redacted]) (" [redacted] "); PX1434 at 001 ([redacted] "); PX7026 ([redacted]) at 185:2-13 ([redacted]). Biocoat's customers, [redacted], directly compare the pricing for Biocoat's thermal-cured solution against Surmodics' UV-cured solutions. PX1571 at 016 ([redacted]

[redacted]); PX1672 at 002 ([redacted]); PX2256 at 001 ([redacted]) ([redacted]).

Indicium 5: Sensitivity To Price Changes. Although the primary concern of medical device manufacturers is a coating's performance, customers of outsourced hydrophilic coatings remain sensitive to price changes. *See e.g.*, PX5002 ([redacted]) ¶¶ 11-13 ([redacted]); PX7025 ([redacted]) at 89:19-90:5 ([redacted]). Multiple customers testified that Surmodics' royalty pricing model prompted them to choose Biocoat over Surmodics. *See* PX7022 ([redacted]) at 82:12-83:4 ([redacted]); PX7009 ([redacted]) at 68:19-69:10; *see also* PX7023 ([redacted]) at 61:13-18 ([redacted]). [redacted] PX5006 ([redacted]) ¶ 7. This customer sensitivity to pricing

and structure leads hydrophilic coating suppliers like Biocoat and Surmodics to adjust their pricing due to the presence, or even assumed presence, of the other. *See infra* at 42-46.

Indicium 6: Distinct Customers. Outsourced hydrophilic coating suppliers serve a distinct class of customers: medical device companies that design and commercialize interventional medical devices that require hydrophilic coatings' high level of performance to safely and effectively navigate through a patient's body. Biocoat and Surmodics both serve companies that need coatings for neurovascular and cardiovascular interventional medical devices, which require particularly high hydrophilic coating performance due to the sensitivity and complexity of navigating the coated device through the patient's tortuous vascular system to reach the brain and heart. *See* PX7019 ( ) at 46:13-47:11 ([redacted]); PX7018 (Borgaonkar (Heraeus) Dep. at 24:9-25:3 (medical devices that typically utilize hydrophilic coatings are those used for cardiovascular, neurovascular, and peripheral vascular procedures). [redacted]. PX7022 ( ) at 144:19-145:6; *see also* PX7044 ( ) at 26:20-27:8 ([redacted]).

Neurovascular and cardiovascular customers' reliance on hydrophilic coatings makes them a key distinct customer base for hydrophilic coating suppliers. Neurovascular customers in particular [redacted] According to Biocoat's then-Senior Director of Marketing, in 2022, [redacted]

[redacted]. PX1182 at 001, tab 'Sheet 1' ([redacted]); *see also* PX7023 ([redacted]) at 77:5-19 ([redacted]). Alembic COO Greg Welsh explained that "[redacted]" for neurovascular catheters and that he is "[redacted]." PX7039 (Welsh (Alembic) Dep.) at 69:11-70:9; *see also* PX7048 ([redacted] at 56:22-56:5 ([redacted]).

ii. The Hypothetical Monopolist Test Confirms Outsourced Hydrophilic Coatings is a Relevant Product Market

In addition to these practical indicia, courts often consider the "hypothetical monopolist test" to define a relevant product market. This test asks, assuming all products or services in the candidate market were controlled and sold by a monopolist, whether that hypothetical monopolist could profitably impose a SSNIP, typically a five to ten percent price increase, on a product or service (if so, that is a relevant market), or whether customers switching to alternative products or services would make such a price increase unprofitable (if so, the market is too narrow). *See, e.g., FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 338 (3d Cir. 2016); *OSF Healthcare Sys.*, 852 F. Supp. 2d at 1075. Economic expert Dr. Aaron Fix's Report demonstrates how application of the HMT shows that outsourced hydrophilic coatings is a relevant product market. PX4000 (Fix Expert Report) at ¶¶ 91-99. Dr. Fix found that because medical device customers lack adequate substitutes for outsourced hydrophilic coatings, the combined

Biocoat/Surmodics can implement a significant price increase without losing sales volume post-merger. PX4000 (Fix Expert Report) at ¶¶ 97-99.

This conclusion is consistent with customer testimony. Customers testified that a five to ten percent increase in the cost of hydrophilic coatings would not be meaningful enough to cause a switch to a hydrophobic or other coating type. *See* PX7040 ([redacted]) at 145:21-146:5 ([redacted]); PX7022 ([redacted]) at 146:3-13; PX7023 ([redacted]) at 38:13-17; PX5003 ([redacted]) ¶ 2. Likewise, customers of outsourced hydrophilic coatings would not switch to producing hydrophilic coatings in-house if the price of outsourced hydrophilic coatings increased by five to ten percent. PX7009 ([redacted] 77:18-78:12; PX5000 (Welsh (Alembic) Decl.) ¶ 8.

B. The Relevant Geographic Market Is the United States

The relevant geographic market is "where . . . the effect of the merger on competition will be direct and immediate" and "must correspond to the commercial realities of the industry." *Advoc. Health Care Network*, 841 F.3d at 468 (quotations omitted). A relevant "geographic market does not need to include all of the firm's competitors; it needs to include the competitors that would substantially constrain [the firm's] price-increasing ability." *Id.* at 469 (quotations omitted). Here, the relevant geographic market is the United States.

Medical devices with hydrophilic coatings must receive FDA approval to be sold within the United States. PX7026 ([redacted]) at 431:20-432:24. For this reason, hydrophilic coating suppliers in the United States formulate their coatings specifically to meet FDA standards. PX7026 ([redacted]) at 55:8-19 ([redacted]

[redacted]). To increase the likelihood of FDA approval for their devices, medical device companies look for a coating supplier that is "[redacted]" they can easily visit that has a history of FDA approval; without these attributes, ex-U.S.-based hydrophilic coating suppliers face significant challenges in competing for U.S.-based medical devices. *See* PX7021 ([redacted]) at 143:7–144:8; PX7020 ([redacted].) at 112:2-114:1. Hydrophilic coatings applied to medical devices intended for sale outside the United States are not viable competitive alternatives for U.S. consumers because the FDA must approve the medical device with the hydrophilic coating before it can be sold to U.S. customers.

C. The Proposed Acquisition Results in Presumptively Illegal Market Shares

The Proposed Acquisition is presumptively illegal. It would significantly increase concentration in the already concentrated outsourced hydrophilic coatings market. In *Philadelphia National Bank*, the Supreme Court held that "a merger which produces a firm controlling an undue percentage share of the relevant market, and results in a significant increase in the concentration of firms in that market, is so inherently likely to lessen competition substantially that it must be enjoined in the absence of evidence clearly showing that the merger is not likely to have such anticompetitive effects." 374 U.S. at 363. Applying this standard, courts have held that "[b]y showing that the proposed transaction . . . will lead to undue concentration in the market . . . , the Commission establishes a presumption that the transaction will substantially lessen competition." *FTC v. Staples*, 970 F. Supp. at 1083 (D.D.C. 1997); *see also Heinz Co.*, 246 F.3d at 715 (same).

To assess market concentration, courts often employ a statistical measure known as the Herfindahl-Hirschman Index ("HHI"). *See Kroger*, 2024 WL 5053016 at *15 ("The generally

accepted measure of market concentration, endorsed by the Merger Guidelines, is the [HHI].") (citing the Merger Guidelines § 2.1).[1] HHIs are calculated by adding the squares of each market participant's individual market share. *Id.* A merger that results in a market with an HHI greater than 1,800 and involves an increase in HHI greater than 100 is presumed to substantially lessen competition. *Id.* A merger is also presumed to substantially lessen competition if the merged firm has a market share of greater than 30 percent. *See, e.g.*, *Phila. Nat'l Bank*, 374 U.S. at 364 ("Without attempting to specify the smallest market share which would still be considered to threaten undue concentration, we are clear that 30% presents that threat."); *IQVIA*, 710 F. Supp. 3d at 378-379.

The Proposed Acquisition satisfies any criteria by which a presumptively unlawful merger is measured. It would result in an HHI of nearly 4,000 in the U.S. outsourced hydrophilic coatings market, and an increase of over [redacted] points, [redacted] surpassing the thresholds that trigger a presumption of illegality.[2] PX4000 (Fix Expert Report) ¶ 114. Moreover, Biocoat and Surmodics together possess a market share of more than [redacted] percent of annual U.S. outsourced hydrophilic coatings sales revenue, with Surmodics' share over [redacted] percent and Biocoat's share exceeding [redacted]

[1] "In the short time in which the 2023 Merger Guidelines have been in effect, multiple courts have cited them as persuasive authority[.]" *Kroger*, 2024 WL 5053016 at *16 (collecting cases). Even under the higher HHI thresholds of the 2010 Merger Guidelines, however, the Proposed Acquisition would still be presumptively unlawful. 2010 Horizontal Merger Guidelines at § 5.3 (defining a "highly concentrated market" as one with an HHI above 2500 and explaining "[m]ergers resulting in highly concentrated markets that involve an increase in the HHI of more than 200 points will be presumed to be likely to enhance market power.").

[2] These market shares are measured by annual U.S. revenues because Biocoat and Surmodics' past competitive wins (and the associated revenue they generate) are predictive of competitive significance into the future. *See United States v. Grinnell Corp.*, 384 U.S. 563, 571 (1966) ("The existence of [monopoly] power ordinarily may be inferred from the predominant share of the market."); Merger Guidelines § 4.4B ("Revenues in a relevant market often provide a readily available basis on which to compute shares and are often a good measure of attractiveness to customers.").

percent. PX4000 (Fix Expert Report) at ¶113, Figure 5. In comparison, other competitors are significantly smaller—only one other firm has more than a [redacted] percent share (Harland). *Supra* at 7-8. The HHI increase and post-acquisition HHI in this case are comparable to mergers that other courts have deemed presumptively anticompetitive. *See, e.g.*, *IQVIA*, 710 F. Supp. 3d at 380 (post-merger HHI of 3,635 and an increase of 997 is "well above the relevant threshold for the FTC to establish its prima facie case"); *Advoc. Health Care*, 2017 WL 1022015, at *7 (HHI increase of 1,782 and total of 3,943 was "well beyond the level that the Merger Guidelines identify as presumptively likely to enhance market power"); *see also United States v. Bertelsmann SE & Co. KGaA*, 646 F. Supp. 3d 1, 37 646 F. Supp. 3d 1, 37 (D.D.C. 2022); *Heinz*, 246 F.3d at 716.

[redacted]

PX4000 ([redacted]) at ¶ 113.

This market share analysis is consistent with internal estimates by Defendants and other market participants. Defendants' own documents [redacted]. *See* PX1504 at 036 ([redacted]) ([redacted])

[redacted]); *see also* *supra* at 6-8.

[redacted], smaller hydrophilic coating competitors see Surmodics and Biocoat as #1 and #2 in the outsourced hydrophilic coatings market. PX7027 ([redacted]) at 39:19-40:9. And customers, from the largest device manufacturers to startups, consistently identify Biocoat and Surmodics as the market leaders. PX7021 ([redacted]) at 147:14-19; PX7022 ([redacted]) at 63:16-64:2, 64:19-65:4, 67:12-68:7; PX7025 ([redacted]) at 63:3-7; PX7023 ([redacted]) at 56:22-57:8. In May 2024, just after the Proposed Acquisition was announced, [redacted] PX3171at 001.

Because the high market shares and HHIs establish a presumption of illegality, the burden shifts to Defendants to try to rebut the presumption by "produc[ing] evidence that 'show[s] that the market-share statistics [give] an inaccurate account of the [merger's] probable effects on competition' in the relevant market[.]" *Heinz*, 246 F.3d at 715 (quoting *United States v. Citizens & S. Nat'l Bank*, 422 U.S. 86, 120 (1975)) (first alteration added).

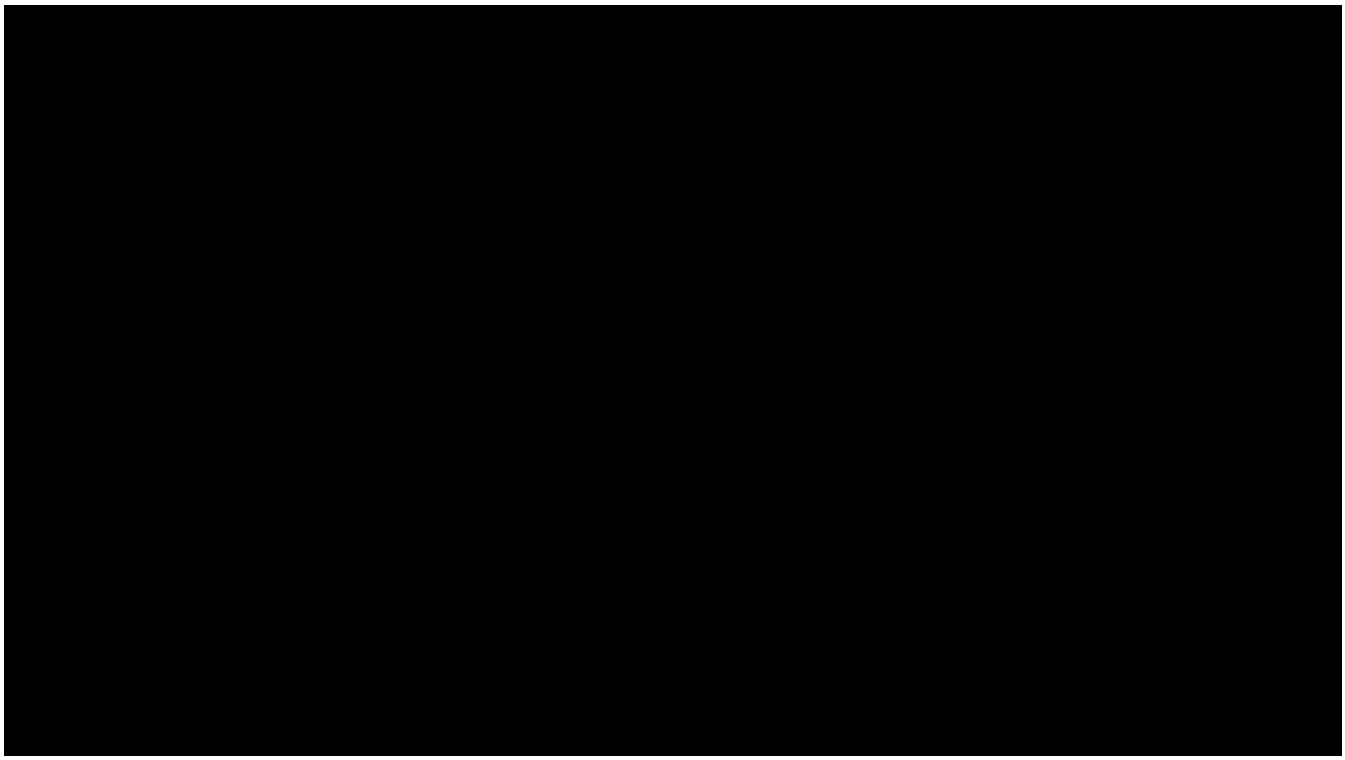
D. The Proposed Acquisition Would Eliminate Substantial Head-to-Head Competition Between Biocoat and Surmodics

The Commission is also likely to succeed on the merits because, in addition to being presumptively unlawful, the Proposed Acquisition would "eliminate substantial head-to-head competition between" two close competitors. *IQVIA*, 710 F. Supp. 3d at 377; *id.* at 382-86; *see also FTC v. Tapestry, Inc.*, 755 F. Supp. 3d 386, 486 (S.D.N.Y. 2024) (quoting *FTC v. Sysco*

Corp., 113 F. Supp. 3d 1, 61 (D.D.C. 2015)) ("Courts have recognized that a merger that eliminates head-to-head competition between close competitors can result in a substantial lessening of competition."); *Sysco Corp.*, 113 F. Supp. 3d at 65 (the proposed merger "between the number one and number two competitors" was likely to lead to unilateral anticompetitive effects); *ProMedica*, 749 F.3d at 568-70 ("Unilateral-effects theory . . . holds that [t]he elimination of competition between two firms that results from their merger may alone constitute a substantial lessening of competition") (quoting 2010 Horizontal Merger Guidelines § 6). "When determining whether there is substantial head-to-head competition, '[c]ourts frequently rely on ordinary course documents and witness testimony illustrating that two merging parties view each other as strong competitors.'" *Kroger*, 2024 WL 5053016, at *17 (quoting *IQVIA*, 710 F. Supp. 3d at 383).

i. Defendants (and Other Industry Participants) View Biocoat and Surmodics as Direct Competitors

Biocoat and Surmodics have repeatedly recognized each other as close competitors. As recently as February 2025, [redacted] PX1294 at 015 (see inset); PX7015 ([redacted]) at 164:20-24 ([redacted]); PX7036 ([redacted]) at 261:2-3.



PX1294 at 015 ( )

Voluminous ordinary course evidence and testimony from both companies and from GTCR reflects this dynamic. *See, e.g.*, PX7020 ( ) at 68:4-14 (" "); PX2107 at 008-009 ( ) ( ); PX1196 at 001 ( ) ( ); PX1101 at 001 ( ); PX7024 ( ) at 261:13-25.

with evidence from customers, who overwhelmingly identify Biocoat and Surmodics as close competitors on multiple dimensions, including coating performance, price, customer service, and innovation.

[redacted] PX7023 ([redacted]) at 71:25-72:6. [redacted] PX5002 ([redacted] ¶ 16 ([redacted]); *see also* PX7045 ([redacted]) at 93:9-11 ([redacted]); PX7048 ([redacted]) at 35:13-36:3 ([redacted]). [redacted]. PX5006 ([redacted]) ¶ 5; *see also infra* at 42-46.

Several of Defendants' largest customers testified that the Proposed Acquisition would consolidate their two primary hydrophilic coating suppliers. [redacted]. PX7023 ([redacted]) at 71:11-24. Likewise, [redacted], explained that [redacted]. PX5002 ([redacted].) ¶ 13. The COO of Alembic, a small medical device company developing neurovascular catheters, testified that he "[redacted]

[redacted] PX5000 (Welsh (Alembic) Decl.) ¶ 7; PX7039 (Welsh (Alembic) Dep.) at 94:6-9 (confirming declaration).

Competitors of Biocoat and Surmodics in the outsourced hydrophilic coatings market likewise agree that the two companies directly and substantially compete. [redacted], [redacted] and [redacted] all view Biocoat and Surmodics as each other's direct competitor. *See* PX7034 ([redacted]) at 141:14-142:7, 224:19-225:9 ([redacted]); PX7019 ([redacted]) at 98:10-16 ([redacted]); PX7027 ([redacted]) at 39:19-40:9 ([redacted]).

ii. Biocoat and Surmodics Compete to Coat the Same Medical Devices

Biocoat and Surmodics compete head-to-head to coat many of the same medical devices, regardless of curing method. The merging parties compete to win business throughout the device development lifecycle, including competition to be considered for a new device, competition to be selected as the coating for a new device, and even competition for a device that has selected a coating and been commercialized.

Head-to-head competition between Biocoat and Surmodics begins long before a specific opportunity arises: they tout the superiority of their coatings versus the other at trade shows, in white papers, in targeted customer outreach, and in testing. *See* PX7026 ([redacted]) at 234:23-235:8 ([redacted]). From the earliest stages of a medical device's development through its commercial launch, Biocoat and Surmodics each strive to convince customers that they offer superior performance at the lowest cost, have the best and cheapest development capabilities to work with customers to optimize the coating's performance, and have the best technological expertise to assist customers with limiting FDA-regulatory

issues. *See, e.g.*, PX7036 (.) at 67:19-70:6; PX5002 ( ) ¶¶ 10-13; PX7043 ( ) at 22:2-16 ( ). Customers not only benefit from the myriad ways Biocoat and Surmodics compete, but they also benefit from the constant competitive pressure Biocoat and Surmodics exert on each other to continue innovating and improving their hydrophilic coatings products and services. *See* PX7023 ( ) at 75:18-76-9; PX7041 ( ) at 133:20-24 (" .").

In order to evaluate coatings for a specific device, customers often ask both Biocoat and Surmodics to coat a prototype of their device to see which company's coating performs better. PX1151 at 007-008 ( ) ( ). This testing is often an example of head-to-head competition based on the technical capabilities of Biocoat's and Surmodics' coatings. *See, e.g.,* PX3021 at 003-007 (Integer, Selection of Hydrophilic Coating for Champion, May 8, 2020) (in 2020, Integer tested UV-cured coatings from Surmodics and Harland along with Biocoat's thermal-cured coating "head-to-head on the same wire" for a cardiovascular guidewire and found that Biocoat performed the best); PX7009 ( ) at 73:23-74:20 ( ); PX7021 ( ) at 163:6-11 ( )

[redacted]); PX7023 ([redacted]) at 68:1-24 ([redacted]). Competition can continue beyond the feasibility phase and into optimization. *See, e.g.*, PX2306 at 002 ([redacted]); *see also* supra at 6, 21-23, 36.

Even when Biocoat and Surmodics are not both selected for feasibility testing, they nonetheless may still compete. For example, in 2023, [redacted]. PX5002 ([redacted]) ¶ 9. [redacted]. PX5002 ([redacted]) ¶ 9. [redacted]. PX5002 ([redacted]) ¶ 9. In another example, [redacted] PX2057 at 001. [redacted]. PX7048 ([redacted]) at 14:2-21, 20:2-6, 34:11-18.

Beyond the head-to-head competition to demonstrate technical qualification of the coating, Biocoat and Surmodics compete to offer the fastest, best, and cheapest technical testing

of prototypes. For example, [redacted] PX2098 at 001. Additionally, [redacted] PX1333 at 001 ([redacted]); PX1445 at 001-003 ([redacted]).

Finally, after a medical device manufacturer has selected a coating and the device has been successfully commercialized, coating suppliers can target each other's customers to try to convert legacy business to their coatings. Recent FDA approvals suggest that a pathway exists for converting coatings on medical devices. [redacted]. PX1561 at 001 ([redacted]); PX7036 ([redacted]) at 119:19-120:8 ("[redacted]."); PX1350 at 055 ([redacted]) ("[redacted]").

As a result, [redacted]. Examples include:

- [redacted].
- [redacted].
- [redacted]
- [redacted].

In February 2024, [redacted]. PX1060 at 002 ([redacted]); PX1122 at 001-005 ([redacted]); PX7024 ([redacted]) at 331:2-332:21. Since late 2023, [redacted]. *See, e.g.*, PX1077 at 001 ([redacted]).

The Proposed Acquisition is already depriving customers of the benefit of competition between Biocoat and Surmodics. In early 2024, [redacted]. PX1554 at 001 ([redacted]); PX5002 ([redacted]) ¶ 17 ([redacted]). [redacted]. PX7036 ([redacted]) at 178:18-179:7 ("[redacted]

[redacted].”). In May 2024, [redacted] PX1109 at 001. In July, after the Proposed Acquisition had been publicly announced, [redacted] PX1547 at 001 (“[redacted]”). In October 2024, [redacted]. PX5002 ([redacted]) ¶ 17. Biocoat’s [redacted]. The Proposed Acquisition threatens to eliminate similar competition across the entire industry.

iii. Competition Between Biocoat and Surmodics Has Led to Decreased Pricing and Increased Innovation

Competition between Biocoat and Surmodics has resulted in increased innovation, better quality coatings, and lower pricing for outsourced hydrophilic coatings. Multiple customers testified that Surmodics’ royalty pricing model prompted them to choose Biocoat instead of Surmodics. *See* PX7022 ([redacted].) at 82:12-83:4, 148:7-149:9, 154:19-155:3

(); *see also* PX7023 ( ) at 61:13-18 ( ). For example, . PX7009 ( ) at 68:19-69:10, 69:18-21.

Ordinary course documents and testimony illustrate that . For example, PX2078 at 001 ( ). . PX2126 at 001.

Additionally, . In an internal July 2024 email, . PX2077 at 001. In June 2024, ” PX1210 at 001-002.

[redacted] PX1210 at 001 ([redacted]). In September 2024, [redacted]. PX2084 at 001-002. [redacted] PX7044 ([redacted]) at 114:12-115:4.

[redacted]. In July 2023, [redacted] PX1222 at 002; *see also* PX1438 at 001 ([redacted]).

[redacted]. In July 2022, for example, [redacted] PX1021 at 001. A [redacted] 2022 "[redacted]

[redacted]." PX2082 at 006; *see also* PX1571 at 006 ([redacted]).

The Proposed Acquisition would also eliminate the competitive pressure Biocoat and Surmodics exert on each other to continue innovating to improve their hydrophilic coating offerings. [redacted]. [redacted]) explained that [redacted]. PX7024 ([redacted]) at 201:9-202:5. [redacted] PX1020 at 001. And in February 2024, just months before the Proposed Acquisition was announced [redacted] PX1122 at 001. Biocoat's [redacted] PX1026 at 031 ([redacted]); *see also* PX1287 at 001-002 ([redacted]) ([redacted]

[redacted]); PX1193 at 001 ([redacted]) ([redacted] [redacted]).

Similarly, [redacted]. [redacted] [redacted]) at 155:10-17. And [redacted] PX7003 ([redacted]) at 170:15-171:1. This increased innovation has benefitted hydrophilic coating customers and threatens to be extinguished by the Proposed Acquisition.

Customer testimony reflects concerns about this loss of competition. "[redacted]" if the merger is consummated, and Alembic's CEO "[redacted]." PX5000 (Welsh (Alembic) Decl.) ¶ 7; PX7039 (Welsh (Alembic) Dep.) at 96:15-98:3, 99:23-100:10. The Proposed Acquisition would similarly eliminate [redacted]. PX7043 ([redacted]) at 12:3-13:19, 14:15-18, 62:22-63:19.

II. Defendants Cannot Rebut Plaintiffs' Prima Facie Case

Defendants cannot rebut the multiple *prima facie* bases for the illegality of the Proposed Acquisition that support Plaintiffs' likelihood of success on the merits. *See Baker Hughes*, 908 F.2d at 982 ("[t]he burden of producing evidence to rebut [the *prima facie* case] then shifts to the defendant"). Even if the record provided support for Defendants' rebuttal arguments—which it does not—any claimed procompetitive effects of the Proposed Acquisition would be inadequate to overcome Plaintiffs' compelling evidence of anticompetitive harm. *See Heinz*, 246 F.3d at 725 ("[T]he more compelling the prima facie case, the more evidence the defendant must present to rebut it successfully"); *OSF Healthcare*, 852 F. Supp. 2d at 1082 (observing that the FTC's "compelling prima facie case based on market concentration levels" made it "more difficult for defendants to overcome the strong presumption of illegality"). Although the burden falls on Defendants, Plaintiffs briefly address their defenses below.[3] The evidence demonstrates that neither entry or expansion, efficiencies, [redacted] can offset the significant competitive harm that is likely to result from the Proposed Acquisition.

A. Entry or Expansion Is Unlikely to be Timely or Sufficient to Preserve Competition

To meet their burden, Defendants must demonstrate that expansion of existing firms or entry by new firms will be "timely, likely, and sufficient in its magnitude, character, and scope to deter or counteract the competitive effects" of the Proposed Acquisition. *FTC v. Sanford Health*, 926 F.3d 959, 965 (8th Cir. 2019); *see also Kroger*, 2024 WL 5053016 at *20 ("[D]efendant must

[3] Plaintiffs will address Defendant's Article III standing defense once Defendants have fully articulated their argument on that issue. Another court in this jurisdiction, however, has found that joining GTCR, LLC as a defendant was appropriate. *D'Angelo v. Sterigenics U.S., LLC.*, 2024 WL 1283582 at *8-10 (N.D. Ill. 2024) (finding Plaintiff was likely to succeed in joining GTCR, LLC on a direct participant derivative liability theory despite the fact that GTCR, LLC was not a parent company of the fund or business at issue, in part because the complaint alleged that GTCR, LLC "controlled, managed, and/or directed" Sterigenics operations through funds).

demonstrate that it is sufficient to fill the competitive void that will result from the merger." (quoting *United States v. H&R Block*, 833 F. Supp. 2d 36, 73 (D.D.C. 2011)) (internal quotation marks omitted). To be timely, entry must occur before the acquisition causes anticompetitive effects and, to be sufficient, must maintain competition over the long term. *United States v. Aetna*, 240 F. Supp. 3d at 52-53 (D.D.C. 2017). None of these factors are present here.

First, developing a new hydrophilic coating demands years of work by a highly specialized research and development team with "[redacted]," and major financial investment. PX7003 ([redacted]) at 211:16-23; PX7027 ([redacted]) at 43:21-44:19 ("[redacted]."). Defendants acknowledge [redacted]. PX0004 ([redacted]) at 055-056; PX0001 ([redacted]) at 067-068. That period is significantly longer for new companies trying to break into the market. For example, Integer, a CDMO, spent more than eight years and several million dollars trying to develop its own hydrophilic coating before abandoning the project due to costs and its inability to produce a sufficiently differentiated product. *See* PX7013 (Senn (Integer) IH) at 25:3-27:3. The substantial time and investment required to enter the hydrophilic coatings market has led even large medical device companies, such as [redacted] and [redacted], to decide against developing their own coatings. *See* PX7023 ([redacted]). at 59:12-60:4; PX7037 ([redacted]) at 147:9-148:6.

Second, even if a company successfully develops a new hydrophilic coating, it typically takes several additional years for a coated device to earn FDA approval [redacted]

[redacted]. *See* PX0001 ([redacted]) at 066-068 ([redacted]); PX0004 ([redacted]) at 063-064 ([redacted]). [redacted]. PX7006 ([redacted]) at 59:23-60:19; *see also* PX7034 ([redacted]) at 235:20-236:16 ([redacted]).

[redacted]. [redacted]. PX0004 ([redacted]) at 063-064. Similarly, [redacted]. PX1014 at 030 ([redacted]); *see also* PX7006 ([redacted]) at 60:20-62:8 ([redacted]).

The highly regulated nature of the medical devices industry also incentivizes medical device companies to rely on established hydrophilic coating suppliers with a long history of FDA approval, rather than new market entrants. PX7021 ([redacted]) at 143:7-144:8.

Customers are generally unwilling to take the risk of applying an unproven hydrophilic coating on their device. PX7036 ( ) at 102:4-18; PX1557 at 001 ( ); PX7030 ( ) at 62:19-64:21; PX1175 at 053 ( ); PX7026 ( ) at 418:15-24. Rather, Defendant and third-party witness testimony and documents show that customers prefer to select a coating supplier with a proven track record of coating FDA-approved medical devices. *See* PX7003 ( ) at 74:6-11 ( ); PX7006 ( ) at 59:23-61:15 ( ); PX1152 at 057 ( ) ("); PX1121 at 006 ( ) (" ."); PX7026 ( ) at 89:9-90:11 ( ).

The experience of , a small medical device company that tried an unproven supplier with disastrous consequences, is instructive. PX7009 ( ) at 34:7-36:5. Forced back to the drawing board,

[redacted].

PX7009 ([redacted]) at 62:11-63:19, 71:4-73:7.

The strong customer preference for using hydrophilic coating suppliers with a long track record of FDA approval, combined with the significant investment of time and money required to bring a new hydrophilic coating to market and wait for it to become profitable, makes entry and expansion extremely unlikely to be able to counteract the Proposed Acquisition's likely competitive harm. *See Heinz*, 246 F.3d at 717 (where entry and expansion are "difficult and improbable," anticompetitive harm is unlikely to be ameliorated by new competition from outsiders); *see also* PX7034 ([redacted]) at 232:23-233:21 ([redacted]).

B. Defendants Will Fail to Demonstrate Efficiencies Outweigh Likely Competitive Harm

The Supreme Court has never recognized an efficiencies defense and "has instead, on three occasions, cast doubt on its availability." *Penn. State Hershey Med. Ctr.*, 838 F.3d at 347. Lower courts that have entertained the defense require that claimed efficiencies be "verifiable and merger-specific," *OSF Healthcare*, 852 F. Supp. 2d at 1088, and when facing "high concentration levels" they have conducted "rigorous analysis" of asserted efficiencies to ensure they "represent more than mere speculation and promises about post-merger behavior." *Heinz*, 246 F.3d at 720; *see FTC v. Univ. Health, Inc.*, 938 F.2d 1206, 1223 (11th Cir. 1991) (explaining that "speculative, self-serving assertions" cannot overcome a "presumption of illegality").

Here, [redacted]. PX1611 ([redacted]; PX7032 ([redacted].) at 141:3-4 ("[redacted]"). As of the end of discovery, [redacted]

[redacted]. PX0001 at 101-02 ([redacted]), referred to in PX0032 at 9 ([redacted].). To the extent Defendants are even advancing an efficiency defense, such efficiencies are not cognizable because they are vague, speculative, and neither verifiable nor merger specific. *See OSF Healthcare*, 852 F. Supp. 2d at 1088. Thus, on balance, any competitive harm that results from the Proposed Acquisition will not be outweighed by procompetitive benefits.

C. Defendants [redacted]

An acquisition violates Section 7 when "the effect of *such* acquisition may be substantially to lessen competition, or to tend to create a monopoly." 15 U.S.C. § 18 (emphasis added). The FTC filed its complaint in March 2025 based on the competitive harm that may be caused by GTCR's Proposed Acquisition of Surmodics which, at that time, [redacted], even when the FTC raised concerns about the Proposed Acquisition. Instead, Defendants [redacted]

[redacted].

Defendants bear the burden to show that any proposed remedy, [redacted] would adequately "offset the competitive harm of the merger," *Kroger*, 2024 WL 5053016, at *28, and create a new competitor that has both the means and incentive to compete effectively against the merged firm. *See Aetna*, 240 F. Supp. 3d at 60; *see also Ford Motor Co. v. United States*, 405 U.S. 562, 575 (1972) ("The divested company needs time so it can obtain a foothold in the industry. The relief ordered should cure the ill effects . . . .") (quotation omitted). Courts have offered guidelines regarding the types of remedies that satisfy this standard, which a final proposal would need to address. For example, a divestiture should generally encompass an entire standalone business or product line—including all personnel, facilities, equipment, and other assets that are vital to the success of the business or product line—rather than pieces of a business that may not succeed without the whole. *See Kroger*, 2024 WL 5053016, at *26 (rejecting proposed divestiture that did "not represent a standalone, fully functioning company"); *Sysco*, 113 F. Supp. 3d at 74 (considering whether facilities included in proposed divestiture would enable buyer to compete with merged firm); *see also id.* at 76 (considering "disadvantages" the divestiture buyer would face from having fewer than half the salespeople of the existing business). [redacted].

III. The Equities Favor a Preliminary Injunction

The equities in this case justify a preliminary injunction. Closing the Proposed Acquisition would immediately harm competition. Without preliminary relief, it may be "more difficult to order effective relief after a trial on the merits by 'unscrambling' merged assets to

'recreate pre-merger competition.'" *Advoc. Health Care*, 2017 WL 1022015, at *16 (quoting *Heinz*, 246 F.3d at 726). Here, the loss of substantial head-to-head competition between Biocoat and Surmodics will be difficult, if not impossible, to reverse should Defendants consummate the Proposed Acquisition before a full merits hearing can take place. "The public has strong interests in the effective enforcement of the antitrust laws and in preserving its ability to order effective relief if it succeeds after a trial on the merits." *Advoc. Health Care*, 2017 WL 1022015, at *16. Preliminarily enjoining a potentially anticompetitive merger plainly serves those interests. *See FTC v. Warner Comm'cns*, 742 F.2d 1156, 1165 (9th Cir. 1984) ("A denial of a preliminary injunction would preclude effective relief if the Commission ultimately prevails.") (citing *FTC v. Great Lakes Chem. Corp.*, 528 F. Supp. 84, 87 (N.D. Ill. 1981)). There is "no reason why, if the merger makes economic sense now, it would not be equally sensible to consummate the merger following [an] FTC adjudication on the merits that finds the merger lawful." *Penn State Hershey Med. Ctr.*, 838 F.3d at 353.

CONCLUSION

Plaintiffs respectfully request that the Court grant the preliminary injunction.

Dated: July 14, 2025

Respectfully submitted,

/s/ Maia Perez

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CERTIFICATE OF SERVICE

Pursuant to Local Rule 5.9, I hereby certify that on this 14th day of July 2025, the foregoing was electronically filed using the Court's CM/ECF system and constitutes service to the attorneys of record who have consented to accept service by electronic means and that GTCR, LLC's, GTCR BC Holdings, LLC's, and Surmodics, Inc.'s counsel of record are being served with a copy of this document via electronic mail.

Dated: July 14, 2025

/s/ Maia Perez
Maia Perez